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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Chandrika Govardhan

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EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/749,962	Applicant(s) GOVARDHAN ET AL.	
	Examiner Suzanne M. Noakes, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 7-10, 11, 13, 14 and 17(a)-22, drawn to a calcium crystal of human growth hormone (hGH) or a hGH derivative, classified in class 530, subclass 399.
 - II. Claims 2, 5-10, 12, 15, 16 and 17(b)-22, drawn to a monovalent crystal of human growth hormone (hGH) or a hGH derivative, classified in class 530, subclass 399.
 - III. Claim 3, 7-10 and 17(c)-22, drawn to a protamine crystal of human growth hormone (hGH) or a hGH derivative, classified in class 530, subclass 399.
 - IV. Claims 4, 7-10 and 17(d)-22, drawn to a polyarginine crystal of human growth hormone (hGH) or a hGH derivative, classified in class 530, subclass 399.
 - V. Claims 23, 26 and 27-32, drawn to a method for treating a mammal having a disorder associated with human growth hormone deficiency, classified in class 514, subclass 12.
 - VI. Claims 24, 25 and 28-32, drawn to a method for inducing weight gain in a mammal by administering hGH crystals, classified in class 514, subclass 12.

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- VII. Claims 33, 36-40 and 45-58, drawn to a method of producing calcium crystals, classified in class 424, subclass 400.
- VIII. Claims 33, 36-38 and 41-59, drawn to a method of producing monovalent cation crystals, classified in class 424, subclass 400.
- XI. Claims 33-35, 45, 46, 51 and 53, drawn to a method of producing protamine crystals, classified in class 424, subclass 400.
- X. Claims 33-35, 45, 46, 51 and 53, drawn to a method of producing polyarginine crystals, classified in class 424, subclass 400.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-IV are directed to related human growth hormone crystals. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, each crystal has its own unique composition which are not obvious variants of one another. For instance, the exact conditions (e.g. salt, temperature, bufferes, pH, protein concentration, and either calcium, monovalent cations, protamine or polyarginine) needed to create each different type of crystal will be unique for each type of crystal produced. Thus, knowing the crystallization conditions and crystal content for one kind of crystal will not necessarily mean that those exact same conditions can be used for the other types of crystals by the mere substitution of

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calcium for monovalent cations, etc. Thus each crystal is a unique and patentably distinct product.

3. Inventions I-IV and V-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the products as claimed can be practiced with another materially different product or (2) the products as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of treating a mammal having a hGH deficiency (Group V) or a method of inducing weight gain in a mammal can be practiced with other hGH crystals such as those found in US patent 6,117,984.

4. Inventions I-IV and VII-X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products as claimed can be made by materially different processes such as small scale protein crystallography methods such as hanging-drop or sitting-drop vapor diffusion methods.

5. Inventions V and VI are directed to related methods which utilize a common ingredient, hGH crystals. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See

MPEP § 806.05(j). In the instant case, the two methods do not overlap in scope because the end point for each method is distinct. Thus, each method will also have completely different and unique method steps in order to achieve the different desired outcomes and different patient populations for which each method will be executed. Therefor the two methods are not obvious variants of one another and as such each method would require its own unique search which would place an undue burden of search upon the examiner.

6. Inventions V-VI and VII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not capable of being used together because the method of producing crystals only end point is just that, producing crystals. Whereas the methods of administering the crystals to subjects merely use the end product of the other Inventions. The methods have no common method steps and no common end points and as such are patentably distinct.

7. Inventions VII-X are directed to related to methods of making hGH protein crystals. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the design or each protein crystallization method is unique to each desired crystal produced. The ingredients used in each method is distinct as

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are the protein crystals produced by said methods. Furthermore, because the art of crystallization/crystallography is so unpredictable, there can be no certainty that what works to produce crystals with one set of conditions will work with any other type of ingredients (e.g. calcium, cations, protamines or polyarginines) and so the methods are not obvious variants of one another. Thus, each method is unique and patentably distinct and search each method would result in an undue search burden upon the examiner.

8. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

9. Claim 23 is generic to the following disclosed patentably distinct species: the disorders listed in claim 26. The species are independent or distinct because each disorder is a separate and unique hGH deficiency which are not obvious variations of one another.

Claims 36 and 37 are generic to the following disclosed patentably distinct species: the ionic polymers listed in claim 55. The species are independent or distinct because each polymer listed are non-obvious and distinct forms on ionic polymers.

Claims 36 and 37 are generic to the following disclosed patentably distinct species: the crystallization buffers listed in claim 57. The species are independent or

distinct because each polymer listed are non-obvious and distinct forms on buffers that can be used in the crystallization methods.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Potential Right to Rejoinder

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.30am to 4.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber or Kathleen Kerr can be reached on 571-272-0925 and 571-272-0931, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SMN

24 May 2006



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SUPERVISORY PATENT EXAMINER